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ABSTRACT

In response to congressional request, this report provides information on the implementation plans developed by the Center for Disease Control (CDC) for the Vaccines for Children (VFC) Program. Introductory material indicates that the VFC was created to increase vaccine coverage levels nationwide by creating an entitlement to free vaccine for VFC-eligible children and thereby reducing vaccine cost as a barrier to immunization. The next sections of the report identify tasks essential to full VFC implementation and describe a study involving: (1) a literature review on barriers to childhood immunization; (2) interviews with CDC and General Services Administration officials; (3) a telephone survey of immunization projects in 49 states and the District of Columbia to ascertain the status of implementation efforts; (4) interviews with drug industry representatives to investigate existing vaccine distribution arrangements; and (5) tours of proposed vaccine distribution facilities. The report summarizes CDC's existing plans, the key assumptions of such plans, and current progress in implementation of seven major tasks: (1) vaccine contract negotiations; (2) provider enrollment; (3) provider reimbursement; (4) order processing; (5) vaccine distribution; (6) accountability mechanisms; and (7) evaluation plans. The final sections focus on unresolved issues and comments by the Assistant Comptroller General. Data on the vaccination rates and schedules are included. Testimony before the Senate by Kwai-Cheung Chan, the director of Program Evaluation in Physical Systems Areas of the Program Evaluation and Methodology Division is included. (AC)

United States General Accounting Office

GAO

Report to Congressional Requesters

July 1994

VACCINES FOR CHILDREN

Critical Issues in Design and Implementation

ED 373 918

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Program Evaluation and
Methodology Division

B-257864

July 18, 1994

The Honorable Dale Bumpers
The Honorable John Danforth
United States Senate

The Honorable Scott Klug
The Honorable Ron Wyden
U.S. House of Representatives

In response to your request, this letter provides information on the implementation plans developed by the Centers for Disease Control (CDC) for the Vaccines for Children (VFC) Program. Although we will provide further information at a later date, as we arranged with your staff, we present our interim findings in this report. We describe how CDC plans to implement the VFC Program, and we provide information relevant to assessing the likelihood that CDC's proposed system will meet the goals of the VFC Program as identified by CDC.

Section 13631 of the Omnibus Budget Reconciliation Act (OBRA) of 1993 created what is commonly referred to as the Vaccines for Children Program to increase vaccine coverage levels nationwide by creating an entitlement to free vaccine for VFC-eligible children and thereby reduce vaccine cost as a barrier to immunization. Other presumed barriers to immunization are addressed in the Children's Immunization Initiative (CII), of which VFC is a part.[1]

CDC and the states will operate the basic components of the VFC Program, which will purchase and distribute vaccine to VFC-enrolled providers for use in immunizing eligible children. The vaccine distribution function will be carried out by the General Services Administration (GSA), while CDC will be responsible for negotiating a price with the manufacturer and consolidating orders from the states. CDC's plans for implementing the national VFC Program call for the system to become operational by October 1, 1994, as mandated by the enacting legislation, which was signed in August 1993.

[1]Other components of the CII include (1) efforts to improve the quantity and quality of vaccine delivery services through grants to support states' Immunization Action Plans, (2) increases in community participation and education for providers, (3) enhanced measurement of immunization status through random telephone surveys, and (4) development of improved and combined vaccines to simplify the immunization schedule.

Results in Brief

We identified seven tasks integral to the full implementation of the VFC Program. We then assessed the status of these tasks as well as their apparent integration. We believe that the original time line to implement the program in one year was very ambitious. With respect to the status of these tasks, we found the following:

1. Vaccine contract negotiations. As of July 5, 1994, 4 of the 15 contracts with vaccine manufacturers had been awarded; 11 remained under negotiation. The CDC time line calls for July contract awards.

2. Provider enrollment. As of June 28, 1994, only five of the immunization projects we surveyed told us they had mailed VFC enrollment forms to potential vaccine providers.[2] Therefore, participation levels among providers are not yet known. CDC's time line had called for states to begin recruiting in May.

3. Provider reimbursement. Although vaccine is provided free under VFC, providers may charge for its administration. CDC has established a maximum administration fee schedule for vaccine providers based on physicians' prevailing charges. OBRA 1993 requires that administration fees to providers be based on the cost of administration. CDC believes that it is impractical to calculate these costs and that a charge-based schedule is necessary to ensure physician participation. It is not clear that CDC has adequately tested these assumptions, but even if CDC is correct, the fees may impose a financial burden on some VFC recipients. We found, specifically, that the proposed administration fee schedule exceeded Medicaid administration fees by as much as $10 in 15 states. This policy appears to be inconsistent with CDC's stated goal for the VFC Program, which is to remove cost as a barrier to immunization.

4. Order processing. CDC's arrangements for training state staff in the use of vaccine-ordering software appear to be on schedule; however, some states have not yet hired or selected the staff who will be using the software. The schedule for testing the hardware and software for handling vaccine orders also appears to leave no margin for error.

5. Vaccine distribution. CDC did not conduct a systematic review of all the options that they identified (public or private) before choosing GSA for vaccine distribution service. As of July 6, 1994, GSA, which will manage the distribution function, had not incorporated the validation of vaccine

[2]Some additional states currently operate universal vaccine delivery programs and may, therefore, be capable of expediting provider enrollment.

packaging and shipping performance into its predistribution implementation schedule. Such validation is necessary to ensure that the vaccine's efficacy is maintained during shipment. Following our discussions regarding plans to ensure the preservation of vaccine potency in transit, GSA officials told us that 3 to 5 months of additional implementation time beyond October 1 would be preferred.

6. Accountability mechanisms. States bear primary responsibility for developing mechanisms to ensure accountability for federally-purchased vaccine. Without any independent means of verifying state data, CDC's use of national data to monitor provider orders would not only fail to detect patterns of misuse, fraud, or abuse but would also risk verifying inappropriate patterns as appropriate behavior.

7. Evaluation plans. CDC does not have an evaluation plan to assess the cost and effectiveness of the VFC Program against the current system.

In addition to the aforementioned difficulties with individual components, CDC has failed to ensure that the components of the program are properly integrated. Because some of these tasks are interdependent and must be performed sequentially, delays in one task (such as contract negotiation) could have significant impact on others (such as readiness to accept orders and deliver vaccine by October 1) and thereby affect overall implementation. In light of the segmented responsibility for implementation and interdependence of tasks, we are especially concerned that the remaining implementation schedule shows little tolerance for delay in any major component if the program is to begin full operation on October 1, 1994.

There is a need for CDC to take the overall responsibility for ensuring that children receive effective vaccine in a timely manner. For distribution purposes, CDC has entered into an agreement with GSA, but has not instructed them to validate shipping processes. GSA has no experience with storing, packaging, and delivering vaccines, and although they have contracted with Federal Express for the delivery of vaccines, officials told us they had neither plans nor formal arrangements to test shipping containers and their performance during delivery.

CDC is developing its own hardware and software system to process orders and plans to test it by mock processing in three states. Based on our prior experience of reviewing systems development in this and other areas, we

believe that the proposed testing procedure for software and hardware may not be able to identify major problems that could subsequently occur.

In addition to our concerns regarding the status of implementation, we note that certain implementation decisions may be counter to CDC's stated program goals. Specifically, CDC is not requiring VFC providers to report the administration of a vaccine to a particular child; yet the CDC acknowledges the importance of instituting tracking systems under its broader Children's Immunization Initiative, and such systems cannot operate without reporting by providers. This failure to impose a tracking system requirement for VFC will present difficulties that other parts of the Children's Immunization Initiative will have to address.

Scope and Methodology

We conducted an extensive review of the literature on barriers to childhood immunization. Next, we examined how CDC plans to develop and implement the proposed VFC Program and summarized information relevant to assessing the program's capacity to meet the goals of the VFC Program as articulated by CDC. In coordination with our examination of CDC's plans, we also reviewed pertinent legislation and legislative history.

We conducted a telephone survey of states' immunization projects between June 28 and July 8, 1994, to ascertain their progress in implementing the VFC Program and any problems they foresee in meeting the proposed implementation schedule, which calls for program operation by October 1, 1994. Projects in 49 states and the District of Columbia responded.

We reviewed CDC documents and held several meetings with various CDC officials to obtain additional information. After examining the VFC Operations Guide, results of CDC's state surveys, and some of the comments provided by interested parties, we prepared a detailed set of questions and conducted in-depth, focused interviews with CDC and GSA officials to ensure that we had a thorough understanding of their latest positions on those issues.

In addition to examining CDC's proposed vaccine delivery system, we examined certain existing systems to determine their capabilities and their lessons for CDC and GSA. The delivery systems we reviewed were not representative of the full universe of vaccine delivery systems; rather, they were systems that we became aware of during the course of our work. Specifically, we held discussions with the Health Industry Distributors

Association, the National Wholesale Druggists Association, and three major vaccine manufacturers. In addition, we toured a Merck distribution facility in Somerset, New Jersey, and the proposed VFC distribution facility in Burlington, New Jersey.

We reviewed the available literature and documentation on these existing systems, observed their operations during site visits, and discussed them with experts. We will not further describe the existing systems in this report, but instead, will refer to them only as they relate to major issues that we believe need to be addressed by CDC. We also interviewed experts in vaccine research and logistics regarding implementation of the proposed VFC Program.

Our work was conducted between June 14, 1994, and July 8, 1994, in accordance with generally accepted government auditing standards.

Background

Within this century, vaccination has been credited with tremendous reduction in the incidence of some infectious diseases. Since 1950, the use of vaccines reduced the number of cases of diphtheria from 6,000 to 3 or 4 per year by 1990, and reduced pertussis cases from 120,000 in 1950 to 4,500 in 1990. Similar huge reductions have been reported for mumps, polio, rubella, hemophilus influenza, and measles.

Vaccines are available to protect against diseases for which there are no treatments, particularly viral diseases such as polio, measles, rubella, mumps, and hepatitis. Moreover, as a preventive health measure, vaccines hold out a possibility of disease eradication that is impossible with curative medicine. The use of vaccine has made possible the worldwide eradication of smallpox, the only disease ever to be made extinct by man. The next disease targeted for eradication by vaccine is polio, which has already been eliminated from the Americas.

Vaccines work by stimulating the immune system without subjecting the recipient to the targeted disease. This prior exposure allows the immune system to mount an effective response much more quickly; usually quickly enough to prevent any invading pathogens from taking hold and producing disease. Vaccines may be in the form of weakened (attenuated) microorganisms, such as measles or polio vaccines, or dead or parts of dead organisms that are still capable of producing a protective response, such as pertussis vaccine. A third group consists of the inactivated toxin

(or toxoid) of a microorganism, such as tetanus toxoid and diphtheria toxoid.

Immunization Coverage

Between 1989 and 1991, several major outbreaks of measles refocused federal attention on vaccinations. Reexamination of statistics from 1985, the last year for which data were available, suggested that the proportion of children who were fully covered by the age of 2 was very low (0-2 years is the period of greatest risk); only 55 percent of preschoolers had received three or more doses of polio vaccines, and only 65 percent were fully vaccinated against diphtheria-tetanus-pertussis (DTP). Half of the measles cases in 1990 were among preschoolers. Of those preschoolers who were eligible for vaccinations, only 20 percent had received them. This low coverage was perceived to be the cause of the outbreaks, and calls were made for measures to boost coverage rates and thereby prevent repetition of the epidemic.

More recent data have suggested that the overall levels of coverage are now much better (see table 1). However, recent studies of immunization patterns in four major cities indicate that, despite these high levels, there are still "pockets" of low coverage rates (see table 2).

Table 1: Vaccination Rates of Children Aged 19-35 Months[a]

Vaccine	1992	1993 January-June	1993 July-September
DTP/DT[b]			
≥ 3 doses	83.0%	87.2%	90%
≥ 4 doses	59.0	71.1	75
Poliomyelitis			
≥ 3 doses	72.4	78.4	80
Hemophilus influenza type b			
≥ 3 doses	28.2	49.6	60
Measles-containing vaccine	82.5	80.8	86
Hepatitis B			
≥ 3 doses	[c]	12.7	16
Completed vaccination schedule			
4 DTP/3 polio/1 MMR[d]	55.3	64.8	72

[a]From Morbidity and Mortality Weekly Report, "Vaccination Coverage of 2-Year-Old Children—United States," 1991-1992, Vol. 42, Nos. 51 and 52, January 7, 1994. Provisional data based on first and second quarters.

[b]Diphtheria-tetanus-pertussis/diphtheria-tetanus.

[c]Data were not available.

[d]Measles-mumps-rubella.

Table 2: Summary of Inner City Vaccine Coverage at 24 Months[a]

Vaccine	Los Angeles Black	Los Angeles Latino	Baltimore	Rochester	Philadelphia Home interview	Philadelphia Actual records
DPT-4[b]	29.4%	46.4%	56.4%	[c]	41.1%	52.8%
Polio-3	40.5	71.7	63.2	[c]	48.5	61.9
MMR-1[d]	66.6	75.5	78.9	[c]	60.8	77.7
Total	**25**	**42**	**53.9**	**70.2%**	**36.6**	**46.8**

[a]From Morbidity and Mortality Weekly Report, "Vaccination Coverage of 2-Year-Old Children—United States, 1991-1992," January 7, 1994, Vol. 42, Nos. 51 and 52; B. Guyer, "The Baltimore Immunization Study," June 1993, p. 8; K. Roughman, "A Study to Increase Immunization Coverage in Inner City Areas," University of Rochester, School of Medicine and Dentistry, Department of Pediatrics, June 30, 1993, p. 37; A. Arbeter, "A Study to Increase Immunization Coverage of Inner City Minority Children in Philadelphia, Pennsylvania," Albert Einstein Medical Center, Department of Pediatrics, Philadelphia, July 2, 1993; and D. Wood, "Increasing Immunizations Among Latinos and African American Preschool Children in Los Angeles," unpublished data.

[b]Diphtheria-pertussis-tetanus; 4 doses.

[c]Data were not available.

[d]Measles-mumps-rubella; 1 dose.

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It has been suggested that the low coverage levels of the late 1980s were due, in part, to the rapid rise in proprietary vaccine prices earlier in the decade.[3] Consistent with this argument, the rationale of VFC is that lowering the cost of vaccines, especially for the poorer sections of the community who show the lowest coverage rates, would remove a significant barrier and boost coverage in this group.

Recommended Immunization Schedule

The VFC Program will provide vaccines in accordance with the schedule established by the Advisory Committee on Immunization Practices (ACIP). Currently, this schedule includes vaccines for measles, mumps, rubella, diphtheria, polio, tetanus, pertussis, hepatitis B, and hemophilus influenza (see table 3). As noted by CDC officials, VFC coverage would be expanded to include the forthcoming varicella and combined vaccines if these were added to the ACIP schedule.

[3]However, see GAO Correspondence to the Honorable John Dingell dated July 21, 1993, and to the Honorable Dale Bumpers dated July 27, 1993, noting problems in linking price changes to low coverage.

Table 3: Recommended Schedule for Immunizations[a]

		Months						Years
Vaccine	**Birth**	**1-2**	**2**	**4**	**6**	**6-18**	**12-15**	**15**	**4-6**
DPT[b]			X	X	X			X	X
OPV[c]			X	X	X				X
MMR[d]							X		X
HIB conjugate[e]									
HbOC/PRPT[f]			X	X	X		X		
PRP-OMP[g]			X	X			X		
Hep B[h]									
Option 1	X	X				X			
Option 2		X		X		X			

[a]Established by the Advisory Committee on Immunization Practices.

[b]Diphtheria-pertussis-tetanus.

[c]Oral polio vaccine.

[d]Measles-mumps-rubella.

[e]Hemophilus influenza type B conjugate.

[f]Hemophilus influenza oligosaccharide conjugate/poly-ribose phosphate tetanus.

[g]Poly-riLose phosphate-outer membrane protein.

[h]Hepatitis B.

ACIP-scheduled vaccines are currently purchased under federal contracts (through CDC) for distribution to public clinics in various states by the appropriate manufacturers. In addition, some states purchase vaccines in bulk from the manufacturer and distribute them to the state's Medicaid providers. Under the VFC Program, vaccine would be purchased in bulk under contracts negotiated by CDC and distributed to providers for administration to children who are (1) Medicaid-enrolled, (2) without health insurance, (3) underinsured (that is, insured under a plan that does not include vaccinations as a benefit), or (4) covered under the Indian Health Services Act, which applies to American Indians and Alaskan Natives. Children who are eligible as a result of being underinsured may only receive free VFC vaccine through a federally qualified health center (FQHC) or a rural health clinic (RHC).

Each of the four groups covered by the VFC Program is currently eligible to receive free vaccine from public health clinics, FQHCs, and RHCs. Thus, the

VFC Program probably will have its impact only on children without any insurance, who will now obtain free vaccine from any enrolled private provider; that is, from more sources than public health clinics, FQHC, and RHC.

Principal Findings

Below, we review CDC's plans to implement the program by summarizing, for each major implementation task, CDC's existing plans, the key assumptions of such plans, and current progress in implementation. The major tasks we cover are (1) vaccine contract negotiations, (2) provider enrollment, (3) provider reimbursement, (4) order processing, (5) vaccine distribution plans, including facility selection, route validation, and package testing, (6) accountability mechanisms, and (7) evaluation plans.

Vaccine Contract Negotiations

A central element of the VFC Program is the bulk purchase of vaccines through federal contracts with vaccine manufacturers. Under the program funded by section 317 of the Public Health Service Act, which provides grants to states for the support of preventive health services, CDC has regularly negotiated contracts for the purchase and distribution of vaccine to states. Under the proposed VFC Program, the agency will negotiate with manufacturers for the purchase of additional amounts of vaccine, estimated on the basis of information provided by states in a CDC survey completed in January 1994. CDC officials told us that a total of 15 contracts must be negotiated for the vaccines covered by the VFC Program and noted that they consider successful contract negotiation critical to the agency's ability to implement the VFC Program by October 1.

CDC officials maintain that the current status of contract negotiations is consistent with the agency's time line, which calls for contracts to be awarded in July, with states' orders submitted to CDC in August, and vaccine shipped from the distribution facility to states and providers in September. However, when we spoke to CDC officials on July 5, we were told that bids had been received on each of the 15 vaccine contracts, but that only 4 of these contracts had been signed, with 11 still under negotiation. Nonetheless, if these negotiations stall over issues aside from purchase price (which is fixed in the bidding process), CDC may continue to make vaccine purchases under current contracts, within the maximum purchase limitation stipulated therein, until September 30, 1994.

CDC's vaccine contracts have normally stipulated both a minimum quantity of vaccine, which the agency is obligated to purchase, and a maximum

quantity of vaccine, above which the manufacturer is not obligated to offer the contract price. We did not conduct a detailed review of CDC's procedure for integrating state survey data to estimate the amount of vaccine that should be purchased under the VFC Program, nor did we review the reasoning behind any quantities identified in the agency's solicitations. However, some state immunization project directors indicated in survey responses to us and to CDC that their states had no accurate data on the number of children who are underinsured or uninsured with which to determine the anticipated vaccine needs.

Provider Enrollment

State and local health departments and state Medicaid agencies are expected to assume an active role in recruiting and enrolling providers into the VFC Program and obtaining provider information necessary for accurate shipment of vaccine. Although states will bear primary responsibility for this function, the VFC Operations Guide dated May 1994 indicates that CDC will (1) mail a program fact sheet to private providers nationwide, (2) supply states with a kit and guidance on provider recruitment efforts, and (3) make an information kit for private providers available to states.

CDC officials told us that, owing to time constraints, the agency is not monitoring the number of providers states have enrolled to date; they plan to assess this from initial vaccine orders. However, to support states' recruitment efforts, CDC has held bi-regional and tri-regional workshops, emphasizing provider recruitment issues; contacted major medical associations about the VFC Program; and mailed introductory letters to private providers.

However, at the end of June, most state immunization projects that we contacted reported they had not mailed initial VFC information to potential providers. Partly to determine the status of provider enrollment efforts, we surveyed state immunization projects between June 28 and July 8, 1994. We contacted immunization projects in 49 states and the District of Columbia. Although CDC's own implementation plans called for states to begin recruiting and collecting signed provider enrollment forms in May, only five state respondents reported having mailed enrollment forms to providers by June 28, and only nine confirmed having mailed providers local VFC information. However, most states we contacted did confirm having received a copy of CDC's provider information kit and a commercial mailing list of state providers.

Provider Reimbursement

While providers may not charge for VFC vaccines per se, the law does authorize them to impose a fee for the administration of the vaccine. According to OBRA 1993, a VFC provider may impose such a fee as long as it "does not exceed the costs of such administration (as determined by the Secretary based on actual regional costs for such administration)." As part of its provider enrollment activities, CDC has established administration fee caps for providers, based on physicians' prevailing charges as provided by the American Academy of Pediatrics.

CDC justifies using physicians' prevailing charges rather than providers' actual administration cost on two bases. One, CDC has concluded that it would be impractical to calculate the cost of vaccine administration. Two, since provider participation is crucial to the success of the VFC Program, CDC considers it necessary to provide a financial incentive for physicians to perform vaccination services. However, neither of these assumptions appears to have been adequately tested. CDC provided no evidence that it has examined the feasibility of computing the actual cost of vaccine administration. Further, there is no indication that CDC attempted to determine provider willingness to participate at reimbursement levels below what they usually charge for vaccine administration.

Using physicians' prevailing charges rather than cost data may result in vaccine recipients' being asked to pay more for their vaccinations. For example, our survey of state immunization project directors indicated that in 15 states, VFC administration fees would exceed Medicaid administration fees by as much as $10 per administration. This is inconsistent with the primary goal of the VFC Program, which is to remove cost as a barrier to immunization. It emphasizes incentives for physician participation at the expense of those children for whom the cost is a supposed to be a real factor.

Order Processing

The processing of vaccine orders will involve coordinated efforts by providers, states, CDC, and GSA. Under CDC's plan, participating providers would place vaccine orders through states, which would be responsible for reviewing and approving the orders before forwarding them to CDC. Although CDC will provide states with computer hardware and CDC-developed order-processing software, states may elect to process orders through a different automated system or manually.

CDC will be responsible for preparing all orders, whether received electronically or otherwise, for transmission either to manufacturers or to

the GSA distribution facility, which will be responsible for assembling vaccine orders and shipping them to the appropriate recipients.

Depending on state policy, providers may consolidate orders under the VFC Program with orders for vaccines financed by section 317 or state funds. States will apportion providers' vaccine orders using a profile submitted annually by each participating provider, in which the provider estimates what proportion of children for whom vaccine is ordered are VFC-eligible. Finally, states will provide these profile data to CDC for allocating the cost of the provider's order across the various funding sources. To reduce burdens on the order-processing system, providers are advised to order a 3- to 4-month supply of vaccines at one time.

The proposed order-processing plans incorporate assumptions about (1) the capacity of states and CDC to manage the volume of orders, (2) the actual functioning of the integrated ordering system, and (3) the capacity and motivation of providers to accurately estimate vaccine needs on at least a bimonthly basis. Each of these assumptions is largely untested.

In the first case, CDC's plans appear to be on schedule for training state staff to use CDC's software; however, some states have not yet hired or selected the persons who will use the software, and the schedule for testing the hardware and software appears to be quite tight. CDC's current schedule calls for systems to be delivered to states in late July, at the close of CDC's scheduled training sessions, and tested, through transmission of mock orders, by the first week of August. Second, even if the demands of this schedule are met, these tests will demonstrate only that the computer systems are functional—not that the order-processing system is capable of accurately and rapidly processing requests from providers in the volume that may be anticipated.

Third, it is unclear how rapidly providers will comply with a bimonthly schedule. Orders of greater frequency could result in much higher demands on the order-processing and distribution systems than are currently anticipated. Moreover, CDC has no evidence that providers can accurately anticipate their vaccine needs, even if one presumes they are motivated to do so. Over time, historical ordering patterns might be accumulated to facilitate physicians' planning, but this guide is only useful to the extent that historical ordering patterns are valid representations of physicians' actual needs.

Vaccine Distribution

Based on October 1993 discussions with vaccine manufacturers, CDC officials concluded that the VFC Program could not be implemented without developing vaccine distribution arrangements separately from its existing contracts with manufacturers. Specifically, CDC concluded that some vaccine manufacturers would not bid on vaccine contracts if the contract for vaccine, which is subject to price caps established under OBRA 1993, included the cost for delivery to individual providers. Agency officials further concluded that the law did not permit CDC to reimburse manufacturers separately for delivery of vaccine purchased under the caps. Consequently, an alternative distribution arrangement was viewed as necessary, and CDC has taken steps to implement such an arrangement.

In seeking alternative distribution arrangements, CDC does not appear to have conducted a systematic review of the options it identified. Although, consistent with the Economy Act, agency officials concluded that vaccine could be more economically distributed through GSA than through private distributors, CDC did not, in our judgment, conduct a systematic review of public and commercial alternatives. In their deliberations, agency officials appear to have accorded greatest weight to an arrangement's capacity to meet the October 1 deadline.

For example, we found that CDC did not explore the use of Department of Defense (DOD) depots currently handling refrigerated vaccines in Mechanicsburg, Pennsylvania, and Memphis, Tennessee.[4] CDC officials indicated that at the time they were contacted by DOD in late February, they had already progressed with alternative plans in collaboration with GSA. Similarly, CDC officials indicated that a potential competitive solicitation for a "prime vendor" of distribution services was rejected based on (1) CDC's inability to confirm that all potential vaccine manufacturers would place their products with third-party commercial distributors, and (2) CDC's concern that the complexities of such a solicitation would have seriously jeopardized the October 1994 implementation date.[5]

[4]DOD officials representing these facilities reported contacting responsible CDC officials in late February. CDC officials confirmed that the contact took place, but did not report acting on DOD's invitation to visit the facilities.

[5]It is difficult to specify the cost of various distribution alternatives with the level of information currently available to states and CDC regarding the number and locations of delivery points and the anticipated frequency of orders. In the absence of more stable data on these two factors, cost estimates for distribution services may require considerable qualification and any potential specifications for competitive bidding by commercial distributors would be quite broad.

The selected GSA facility, located in Burlington, New Jersey, currently handles approximately 5,000 commodities, including office products, paper, hardware, tools, paint, solvents, and adhesives. At the time we visited the facility on July 6, 1994, the space in which vaccines will be stored and packaged had been cleared of previous stock and was undergoing renovation in preparation for delivery of freezers.

Among the distribution facilities to be employed in implementing the VFC Program, we have reviewed only the federal distribution facility and associated plans. Consequently, we cannot assess the capacity or readiness of the alternative distribution arrangements on which many states will rely. Under the implementation plan developed by CDC, states have been permitted to choose among three vaccine distribution options: (1) using their own distribution facilities, (2) relying on CDC's distribution arrangements with GSA, or (3) using some combination of the two. As of June 30, 1994, 21 states had instructed CDC that they preferred to rely entirely on their own distribution facilities for delivering vaccines to VFC-enrolled providers; 23 states and the District of Columbia will rely at least partly on the GSA arrangement, including 10 states that will rely on GSA exclusively.

GSA officials told us that arrangements to test vaccine packaging and to validate its performance on planned shipping routes had not been formally initiated or incorporated in their already tight schedule for beginning distribution operations. CDC had not instructed GSA to validate shipping processes. Although GSA has contracted with Federal Express for delivery of vaccines, officials told us they had neither plans nor formal arrangements to test shipping containers and their performance during delivery. This is significant because proper shipment of vaccines requires that the temperatures to which the vaccines are exposed do not fall outside manufacturers' specified limits for periods long enough to damage the vaccine's potency. Following discussions with us regarding provisions for safeguarding vaccines during transit, GSA officials acknowledged that they would prefer to have an additional 3 to 5 months of implementation time beyond October 1.

To ensure preservation of vaccine potency and to prevent unnecessary returns due to packaging failure, manufacturers reported taking two interdependent steps: testing of packaging and validation of packaging performance across delivery routes. First, packaging is tested to determine whether it is capable of maintaining an appropriate temperature range under the conditions likely to be encountered in delivery. These tests may

include efforts to identify the most efficient or lightweight packaging capable of meeting these needs. Second, delivery systems are tested to ensure that the product is maintained within acceptable parameters during actual delivery conditions across the various routes and during the different seasons in which the product is shipped. For example, the conditions to which the product will be exposed in a southern state in July will be much different than conditions in Maine in the same month. The only way to be sure that vaccine will arrive safely in each of these conditions is to validate the containers and packing materials (for example, quantity of coolant) in regional conditions to ensure vaccine potency and minimize waste.

Although some manufacturers enclose temperature indicators in each package, distributors have suggested to us that these devices have reliability problems. In addition, some detect only that a particular temperature was exceeded, not the amount of time the product spent outside the recommended temperature range. Finally, the use of temperature indicators may add unnecessarily to shipping expenses if package integrity can be otherwise ensured.

CDC indicates that by the October 1, 1994, implementation date, the VFC Program will voluntarily comply with all federal and state requirements pertaining to vaccine manufacture, storage, and distribution in the private sector. This will include compliance with regulations implementing the Federal Food, Drug, and Cosmetic Act, such as relevant good manufacturing practice requirements, and with state licensing requirements under the Prescription Drug Marketing Act of 1987.

Accountability Mechanisms

The task of ensuring accountability falls largely to states. Among other responsibilities, states must (1) maintain quality control of vaccine ordering and distribution, (2) routinely evaluate VFC Program operations, and (3) guard against fraud and abuse.

CDC officials commented that they anticipated that states would shift resources to accommodate the burden of ensuring accountability, noting that fewer state resources would now need to be devoted to retrospective surveys of immunization status. Currently, some states plan to ask that providers submit usage reports indicating, for example, the number of doses administered by antigen and age of child.

CDC considers it crucial to maintain a balance between accountability and provider participation and believes that accountability measures may impose disincentives for provider participation. Accordingly, the agency advised the states that "although measures against fraud and abuse are appropriate, the effect such measures will have on provider participation must be considered."[6] The law specifically prohibits the states from imposing additional qualifications or conditions on providers, except as the Secretary may permit, in order to prevent fraud and abuse.

States are advised to match information from provider profiles (which estimate numbers of VFC-eligible children in the provider's practice) with ongoing data collected from the ordering process. CDC officials noted that incoming orders should reflect provider profiles and be consistent with the provider's previous ordering patterns, but they also acknowledged that these profiles would initially be difficult to complete. States are supposed to identify orders inconsistent with these patterns, but CDC provided no mechanisms or instructions for what states were supposed to do in such cases other than communicate with the provider. This practice presumes that past ordering patterns reflect actual needs, a fact that states could presumably check through reviewing the number of eligibility forms that providers have collected from vaccine recipients.

Other CDC methods of maintaining accountability were unclear. For example, CDC said they would manage accountability by apportioning orders according to funding source and correlating these apportionments with provider profiles. By apportioning orders by funding source, CDC could then draw down state accounts—for example, VFC, section 317, or state funding—according to apportionment. CDC believes this method would help in maintaining appropriate levels of vaccine inventory by funding source. CDC also expects this mechanism to provide a basis for calibrating entitlement group sizes, which will give the agency another means of establishing appropriate ranges of provider orders.

However, under this process, CDC would have no information other than that provided by the states to detect patterns of misuse, fraud, or abuse. Patterns of misuse, fraud, or abuse embedded in state data would be repeated at the national level. Without any independent means of verifying state data, CDC's use of national data to monitor state and provider orders would not only fail to detect patterns of misuse, fraud, or abuse but would also risk verifying inappropriate patterns as appropriate behavior.

[6]Vaccines for Children Operations Guide, Centers for Disease Control, 1994, p. 42.

For states that do not employ vaccine usage reports, CDC has recommended other methods of ensuring accountability. These include (1) analyzing state population figures to compare public vaccine purchases against annual birth rates; (2) conducting clinic reviews to ensure proper vaccine storage, handling, inventory, and compliance with recommended schedules for vaccine administration; (3) conducting spot checks among providers who order the greatest amount of vaccines; (4) analyzing the frequency of orders; (5) preparing reports comparing vaccine ordering patterns of different providers with their client population size; (6) preparing reports analyzing current vaccine purchase amounts with past ordering patterns; (7) conducting random sample surveys among providers; and (8) enforcing state policies establishing proper vaccine handling and appropriate accountability.

Evaluation Plans

CDC officials told us that the agency has not formed plans for evaluating the VFC Program, but that it is currently in the process of forming a working group to discuss program evaluation strategies. The goal of the VFC Program is to improve immunization rates for all antigens to 90 percent by 1996. However, CDC knows neither what proportion of private providers nor which specific providers would have to be recruited in order to obtain a 90-percent immunization goal. Moreover, there is no way to ensure that VFC will be successful in reaching the "pockets of need" that still exist, because the current reporting system is designed in such a way that it does not track the children who have been immunized. Further, CDC has specifically discouraged states from requiring specific data elements or information from providers, which would enable states to link VFC data to a state registry for tracking children's immunization status. As we have reported earlier, the savings on vaccine costs that may derive from bulk purchasing programs

"will do little to improve preschool immunization levels unless funds are provided for educating parents and tracking and following up on the immunization status of children to help ensure that preschool children receive timely immunizations."[7]

Unresolved Issues

Our examination of the system proposed by the CDC and discussions with experts, manufacturers, and state officials leads us to believe that several important issues remain unresolved. The success of the national program

[7]U.S. General Accounting Office, Childhood Immunization: Opportunities to Improve Immunization Rates at Lower Cost (GAO/HRD-93-41, March 24, 1993).

depends, among other factors, on whether the system proposed by the CDC can be up and running by the October 1 deadline without major problems.

With regard to the operation of CDC's proposed VFC Program, only 2 months are set aside for testing the hardware and software system. Based on our experience of reviewing systems development in this and other areas, we believe it is unlikely that testing the system through a procedure of processing mock order forms in three states, as CDC proposes, will be sufficient to identify major problems that may occur. What CDC is suggesting can be considered, at best, developmental testing. Realistic operational testing is necessary, but there is no provision for this within CDC's proposed time frame. Further, even if CDC's developmental testing methods were excellent, there would still be insufficient time between the initiation and completion of testing for any major problems to be rectified.

With regard to the operation of the GSA's proposed distribution system, there is no time allocated for validation of the shipping containers. With only 2 months left for the system to be operational, we believe that if GSA and CDC choose to initiate testing now, this period is unrealistically short. Further, because those states that will not use the GSA system exclusively will have to modify their own systems, they will have to test their systems both internally and in cooperation with the CDC and GSA.

Therefore, whether CDC can implement its system by October 1, 1994, remains unclear in the face of major implementation hurdles.

The VFC Program aims to increase vaccination coverage rates by removing vaccine cost as a barrier to vaccination. Most recent studies, including those of four inner city areas where the undervaccinated tend to be concentrated, indicate that vaccine cost is not an important barrier. Although lower economic status is definitely associated with undervaccination, this relationship does not appear to function through cost but rather through other factors associated with poverty. Moreover, most children who are undervaccinated are eligible for free vaccine under the present system.

In other words, most recent literature suggests that it is unlikely that the provision of free vaccines through VFC will boost coverage in the most affected groups, for whom vaccines are already free, or among other groups when previous experience strongly suggests that this is not an important consideration for the parents. More promising strategies might address what are widely acknowledged to be the more important barriers,

which include provider behavior, lack of knowledge and awareness of the vaccine schedule on the part of parents, and problems of access.

It will also be extremely difficult to assess VFC's impact. VFC is only one part of the wider Children's Immunization Initiative, which has five components. If coverage increases, it may be in spite of the VFC Program; whereas if it falls, it may be because of the failure of other parts of the initiative.

Recommendations

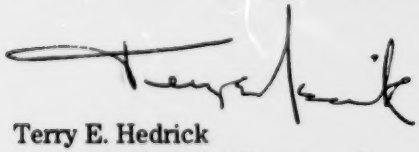
We are not making any recommendations in this report.

Agency Comments

As requested by your staff, we did not obtain written comments from the Department of Health and Human Services on a draft of this report. However, we provided an oral summary of our findings and conclusions to responsible officials of CDC, National Vaccine Program Office, Public Health Service, and GSA. They offered some clarifications of the reasons for implementation decisions, which we have incorporated in the report where appropriate. Based on our discussions, CDC officials recognized that the issue of package testing is important and stated that they will work with GSA on this issue. CDC officials believe that they have the expertise necessary to resolve these issues and will have the VFC Program in place by October 1, 1994.

As agreed with your offices, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time, we will send copies to the Secretary of Health and Human Services, the Director of the Centers for Disease Control, the Administrator of General Services, and other interested parties, and we will make copies available to others upon request.

If you have any questions or would like additional information, please call me at (202) 512-2900 or Kwai-Cheung Chan, Director of Program Evaluation in Physical Systems Areas, at (202) 512-3092. Other major contributors to this report are listed in appendix I.



Terry E. Hedrick
Assistant Comptroller General

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Testimony

Before the Subcommittee on Labor,
Health, Human Services, and Education
Committee on Appropriations
United States Senate

For Release on Delivery
Expected at 2:00 p.m.
Thursday
July 21, 1994

VACCINES FOR CHILDREN

Major Implementation Hurdles Remain

Statement of Kwai-Cheung Chan
Director of Program Evaluation
in Physical Systems Areas
Program Evaluation and Methodology Division

PS 022695

Mr. Chairman and Members of the Subcommittee:

It is my pleasure to be here today to present information on the implementation plans developed by the Centers for Disease Control (CDC) for the Vaccines for Children (VFC) Program. My statement is based upon our report entitled Vaccines for Children: Critical Issues in Design and Implementation, which we issued on July 18, 1994. In our testimony today, we will describe how CDC plans to implement the VFC Program, and provide information relevant to assessing the likelihood that CDC's proposed system will meet the program's goals as identified by CDC. First, however, I will provide some basic information on the VFC Program and briefly describe the work we conducted in response to your request.

I would like to begin by underscoring the importance of vaccination. Within this century, vaccination has been credited with tremendous reduction in the incidence of some infectious diseases, including the worldwide eradication of smallpox and the elimination of polio from the Americas.

What is commonly referred to as the Vaccines for Children Program is designed to increase vaccine coverage levels nationwide by creating an entitlement to free vaccine and thereby reducing vaccine cost as a barrier to immunization for four groups of children. These four groups are: (1) Medicaid-enrolled children; (2) children without health insurance; (3) underinsured children (that is, children insured under a plan that does not include vaccinations as a benefit), and (4) children covered under the Indian Health Services Act, which applies to American Indians and Alaskan Natives. Other presumed barriers to immunization are addressed in the administration's Children's Immunization Initiative, of which VFC is one part.

CDC, the General Services Administration (GSA), and the states will operate the basic components of the VFC Program: the purchase of vaccine and its distribution to VFC-enrolled providers (that is, physicians in private practice as well as public health clinics) for use in immunizing eligible children. CDC will be responsible for negotiating a price with the vaccine manufacturers and consolidating vaccine orders from the states; GSA will carry out the vaccine distribution function. The states are responsible for enrolling providers, submitting providers' orders to CDC, and ensuring program accountability. CDC's plans for implementing the national VFC Program call for the system to become operational by October 1, 1994, as mandated by the law.

METHODOLOGY

To answer your questions, we conducted four types of activities. First, we reviewed the literature on barriers to childhood immunization and agency documents related to program implementation. Second, we interviewed officials of CDC and GSA, and conducted a telephone survey of immunization projects in 49

states and the District of Columbia to ascertain the status of their implementation efforts. Third, to learn more about existing vaccine distribution arrangements, we interviewed experts and interested parties, including the National Wholesale Druggists Association, the Health Industry Distributors Association, three major vaccine manufacturers, and experts in vaccine research and logistics. Finally, to supplement our conversations with GSA officials, we toured the proposed GSA vaccine distribution facility in Burlington, New Jersey, as well as a nearby vaccine distribution facility operated by Merck. Our work was conducted between June 14, 1994, and July 8, 1994.

STUDY RESULTS

Before discussing our specific findings, we would like to note that the original plan to implement the VFC program by October 1 was very ambitious given the scope, inherent complexity of tasks, and the need for strong leadership to coordinate the efforts of various federal, state, and private sector partners.

By examining the status of several tasks that are integral to program establishment and operation, we found that the current implementation schedule will not allow for delay in any major tasks and that, as of July 6, this already challenging schedule did not incorporate plans for testing vaccine shipping arrangements. Some of the tasks we examined are interdependent and must be performed sequentially, so delays in one task (such as contract negotiation) could have significant impact on others (such as readiness to accept orders and deliver vaccine by October 1) and thereby affect overall implementation. The distribution of responsibilities across CDC, GSA, and states may increase the potential for miscommunication and consequently delay implementation.

First, I will describe the major components of the proposed VFC Program and assess the likelihood that the program will be fully operational on October 1, 1994. Second, I will summarize information relevant to assessing the program's capacity to meet its goals, as articulated by CDC.

Major Program Components

We reviewed seven program components that CDC must put in place for the program to be fully operational by October 1. These seven components are critical to the implementation and effectiveness of the VFC, but are by no means the only components that need to be in place. In this section of my testimony, I will discuss four of these components: (1) vaccine contract negotiations; (2) provider enrollment; (3) order processing; and (4) vaccine distribution plans, including the selection of a distribution facility and the testing of vaccine packaging. The other three components--(5) provider reimbursement, (6)

accountability mechanisms, and (7) evaluation plans--will be discussed in the context of program goals.

Vaccine Contract Negotiations

The program requires that vaccine be purchased in bulk under federal contracts with manufacturers. CDC officials maintain that the current status of contract negotiations is consistent with the agency's time line, which calls for contracts to be awarded by the end of July, with states' orders submitted to CDC in August and vaccine shipped from the distribution facility to states and providers in September. However, when we spoke to CDC officials on July 5, we were told that although bids had been received on each of the 15 vaccine contracts, only 4 of these contracts had been signed, with 11 still under negotiation.

Provider Enrollment

Most state officials told us that they have just begun efforts to recruit providers to participate in the VFC Program. Although CDC has conducted several activities to support state efforts, only five state immunization projects reported to us that they had mailed enrollment forms to potential providers by the end of June. CDC's plans had called for states to begin collecting signed enrollment forms in May. CDC officials told us that, owing to time constraints, the agency is not monitoring the number of providers states have enrolled; they plan to assess this from initial vaccine orders.

Order Processing

States will be responsible for receiving and approving vaccine orders from VFC-enrolled immunization providers. With respect to order processing, CDC's plans appear to be on schedule for training state staff to use CDC's order-processing software; however, some states have not even hired or selected the persons who will use the software. Moreover, the schedule for testing the hardware and software appears to be quite ambitious. CDC's current schedule calls for systems to be delivered to states in late July, at the close of CDC's scheduled training sessions, and tested, through the transmission of mock orders, by the first week of August. Even if CDC meets the demands of this schedule, their tests are only sufficient to demonstrate that the computer systems are functional--not that the order-processing system is capable of accurately and rapidly processing requests from providers in the volume that may be anticipated.

Vaccine Distribution

Based on discussions with vaccine manufacturers, CDC officials concluded that manufacturers were reluctant to deliver vaccine directly to the anticipated 70,000 providers under the

capped price. Therefore, CDC found it necessary to develop an alternative distribution system. However, CDC does not appear to have conducted a systematic review of distribution options before settling on the use of a GSA distribution facility in Burlington, New Jersey. In their deliberations, agency officials appear to have accorded the greatest weight to the October 1 deadline.

While reviewing the plans for distributing vaccine under the VFC Program, we questioned GSA and CDC officials about plans to test the performance of vaccine packaging along various delivery routes to ensure the preservation of a vaccine's potency. GSA officials told us that such arrangements had not been formally initiated or incorporated in their already tight implementation schedule. Moreover, CDC had not instructed GSA to validate shipping processes. This is significant because proper shipment of vaccines requires that the temperatures to which the vaccines are exposed do not fall outside manufacturers' specified limits for periods long enough to damage the vaccine's potency.

Following discussions with us regarding provisions for safeguarding vaccines during transit, GSA officials acknowledged that they would prefer to have an additional 3 to 5 months of time beyond October 1 to implement the program.

In summary, CDC faces many major implementation hurdles if it is to have an operational program by October 1, 1994.

VFC Program Goals

In addition to reviewing the status of VFC implementation plans, we have developed information relevant to assessing the program's capacity to meet its goals, as articulated by CDC--to increase vaccination coverage rates by removing vaccine cost as a barrier to immunization. We found that two of the major implementation decisions made by CDC may be at odds with the program's stated goals and that the agency has not developed an evaluation plan to compare the cost and effectiveness of VFC to the present system.

Provider Reimbursement

While providers may not charge for vaccines under the VFC program per se, the law does authorize them to impose a fee for the administration of the vaccine. According to the Omnibus Budget Reconciliation Act of 1993, a VFC provider may impose such a fee as long as it "does not exceed the costs of such administration (as determined by the Secretary based on actual regional costs for such administration)." As part of its provider enrollment activities, CDC has established administration fee caps for providers based on physicians' prevailing charges as provided by the American Academy of Pediatrics rather than based on actual costs of administration.

However, CDC provided no evidence that it has examined the feasibility of computing the actual cost of vaccine administration. There is no indication that CDC attempted to determine provider willingness to participate at reimbursement levels below what they usually charge for vaccine administration.

Using physicians' prevailing charges rather than cost data may result in vaccine recipients' being asked to pay more for the administration fee than the law stipulates. This would be inconsistent with the primary goal of the VFC Program, which is to remove cost as a barrier to immunization. Using prevailing charge data appears to promote incentives for physician participation at the expense of those children for whom cost is supposed to be a real factor.

There are also unresolved issues as to the importance of cost as a barrier to increasing immunization rates. As we have reported earlier, the savings on vaccine costs that may derive from bulk purchasing programs

> "will do little to improve preschool immunization levels unless funds are provided for educating parents and tracking and following up on the immunization status of children to help ensure that preschool children receive timely immunizations."[1]

The VFC Program aims to increase vaccination coverage rates by reducing vaccine cost as a barrier to vaccination. Yet most recent studies, including those of four inner city areas where the undervaccinated tend to be concentrated, indicate that vaccine cost is not an important barrier. Lower economic status is associated with undervaccination; however, this does not appear to be attributable to cost but rather to other factors associated with poverty. Moreover, most children who are now undervaccinated are eligible for free vaccine under current programs. At your request, we will be providing further information on this issue at a later date.

Accountability Mechanisms

CDC considers it crucial to maintain a balance between accountability and provider participation and believes that accountability mechanisms may impose disincentives for provider participation. Accordingly, the agency's current reporting system does not require providers to report which children receive vaccinations. Further, CDC has specifically discouraged states from requiring specific data elements or information from

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[1]U.S. General Accounting Office, Childhood Immunization: Opportunities to Improve Immunization Rates at Lower Cost (GAO/HRD-93-41, March 24, 1993).

providers, which would enable states to link VFC data to a state registry for tracking children's immunization status. This means that CDC will find it difficult to detect misuse, fraud, or abuse patterns and that the benefits of tracking systems for increasing immunization rates will be lost.

Evaluation Plans

On July 6, CDC officials told us that the agency has not formed plans for evaluating the VFC Program. However, determining the specific impact of the VFC Program will be difficult without collecting baseline information prior to implementation.

Although the goal of the VFC Program is to improve immunization rates for all antigens to 90 percent by 1996, CDC could identify neither the proportion of providers who must enroll nor where recruitment efforts should be concentrated in order to meet the 90-percent goal. It will admittedly be difficult to assess VFC's impact as distinct from the impact of other components of the Children's Immunization Initiative.

In conclusion, our review indicates that it is unlikely that CDC can fully implement the VFC Program by October 1, 1994, and raises questions about whether VFC, when fully implemented, can be expected to substantially raise vaccination rates. Finally, unless plans for an evaluation of the program are included in its design, we may be unable to determine its impact on vaccination rates.

Mr. Chairman, this concludes my opening remarks. I would be happy to answer any questions you or members of the Subcommittee may have.

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